K103578

510(k) Summary

(Refer to 21 C.F.R. § 807.92)

JUN - 2 2011

a. Submitted by

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b. Contact Person

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c. Device Name

Proprietary/Trade Names:	Philips NM3 Respiratory Profile Monitor with VentAssist, Model 7900
Common Name:	multiparameter monitor (monitoring spirometer, CO_2 monitor, pulse oximeter and cardiac output monitor with partial rebreathing valve).
Classification:	Class II, 21 C.F.R. 868.1850, 868.1400, 870.2700, 868.5675

d. Predicate Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for predicate devices. The predicate devices are as follows:

1.	Philips NM3 Respiratory Profile Monitor	K091459
2.	Bicore CP-100 Cardiopulmonary Monitor	K900696
3.	Puritan Bennett Model 840 Ventilator with PAV+	K053388
4.	Dräger EvitaXL with Option SmartCare	K051263

e. Device Description

The *NM3 monitor with VentAssist* is intended for non-invasive monitoring of the inspired and expired airflow and airway pressure of intensive care unit (ICU), anesthesia and emergency room (ER) patients, as well as capnography and pulse oximetry in all of these clinical settings. It is intended to serve all of the same purposes as the flow, carbon dioxide, pulse oximetry, and cardiac output monitoring components of the predicate *NM3* monitor with the addition of the optional VentAssist software.

Combination CO_2 adapter/flow sensors (neonatal, pediatric, adult), combination adult CO_2 adapter/flow sensors with a partial rebreathing valve and flow sensors (infant/neonatal, pediatric/adult) are connected with a male pneumatic connector to the *NM3 monitor.* Sidestream airway adapters and nasal cannulas are available which are connected with a sample cell connector to a receptacle on the LoFlo Module which can be interfaced to the

NM3 monitor. All of these sensors are already legally marketed as accessories of 510(k) cleared Respironics-Novametrix *NM3 monitor*. The pulse oximetry sensors are connected to the NM3 monitor via a connector on the front panel of the monitor. All of the pulse oximetry sensors are already legally marketed as accessories of the 510(k) cleared *NM3 monitor* and Masimo predicate devices.

The principal function of the flow portion of combination sensors and flow sensors is to provide a differential pressure signal related to flow and airway pressure relative to atmospheric pressure. These sensors are often placed in the breathing circuit between the endotracheal tube and the ventilator circuit Y piece and may also be used in conjunction with a face mask or mouthpiece. The flow measurement portion of the *NM3 monitor* consists of a microprocessor-based data acquisition system that measures flow, and pressure and interfaces with a Capnostat 5 CO_2 sensor. The CO_2 airway adapter portion of the combination sensors, allow the Respironics-Novametrix CO_2 mainstream gas sensor, the Capnostat® 5, to attach to it and measure the concentration of CO_2 in the airway using infrared technology. When CO_2 measurements are combined with airway flow and volume measurements, other parameters such as CO_2 production and dead space can be calculated in all patient populations. The Capnostat 5 sensor as a mainstream gas analyzer includes a sample cell positioned in the breathing circuit through which a patient's inspiratory and expiratory gases flow. The LoFlo module, a sidestream type of gas analyzer, samples gases at 50 ml/min from a sampling port in an adapter placed in a breathing circuit or from a nasal or oral cannula. The gas then passes through a sampling tube to the sample cell, where the gas components are measured. The combination adult CO_2 adapter/flow sensors with a partial rebreathing valve with periodic activation of the rebreathing valve allow pulmonary capillary blood flow and cardiac output to be calculated using the differential Fick method.

The VentAssist software option comprises a new screen with a soft key that provides on-demand ventilator-independent open-loop advice with respect to the level of pressure support and ventilation. As an advisory system, the clinician can choose to accept or reject the advice, alleviating any issues of safety and effectiveness. Additionally, an improved method for the calculation of plateau pressure has been included, as well as a new calculated parameter for work of breathing (WOB). The WOB parameter facilitates the goal of reducing excessive work of breathing per minute, or power of breathing (WOB/min), for mechanical ventilatory support in patients with respiratory failure. The WOB/min parameter is implemented using an Artificial Neural Net (ANN) and is used by the PS/V Advisor software. The VentAssist PS/V Advisor is a rule based system which provides on-demand advice for the setting of the PSV level and ventilator support levels, based upon WOB/min, breathing frequency, tidal volume, ideal body weight, and end-tidal CO_2. The advice is based upon a set of logic rules developed and refined in conjunction with experienced critical care clinicians at teaching University hospitals. Decision support advice offered by the VentAssist software is available during monitoring of adult patients. The monitor uses the sensor-type (adult, pediatric, or neonate), as well as patient data entered into the monitor, to enable appropriate features.

f. Intended Use

The intended use of the Philips NM3 Respiratory Profile Monitor, Model 7900, is to provide:

- cardiac output monitoring via the method of partial rebreathing in adult patients receiving mechanical ventilation during general anesthesia and in the intensive care unit (ICU).

- spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency

department (ED). Separate combination CO_2/flow sensors are provided for adult, pediatric and neonatal use.

- continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED).

The intended use of the VentAssist software option is to provide:

- non-invasive monitoring of work of breathing per minute in adult patients receiving pressure support mechanical ventilation.

- on-demand advice in mechanically ventilated adult patients as prescribed by the caregiver regarding (a) modifications to the current pressure support settings in order to assess the work of breathing and breathing pattern and (b) modifications to ventilation in order to maintain end-tidal CO_2 in a range determined by the physician. The patients should be hemodynamically stable and must be breathing spontaneously.

g. Technological Characteristics

The previously cleared *NM3 monitor* contains a flow and carbon dioxide monitoring component consisting of the previously 510(k) cleared *Mercury module with Capnostat 5,* a pulse oximetry component consisting of the previously 510(k) cleared *Masimo Rainbow Set OEM module*, and a cardiac output monitoring component. The *Mercury module with Capnostat 5* provides continuous monitoring of respiratory flow and pressure, and CO_2. Additionally, besides the Capnostat 5 sensor, the previously cleared LoFlo C5 sidestream module may be interfaced to the Mercury Module. The *Masimo Rainbow Set OEM module* provides continuous monitoring of SpO_2 and pulse rate. The cardiac output monitoring component provides cardiac output measurement capabilities using the partial CO_2 rebreathing method. The VentAssist software option provides additional screens to display parameters in the predicate Philips NM3 Monitor in a bar chart format, and adds a new work of breathing (WOB/min) parameter computed with a fixed Artificial Neural Net (ANN). A new user-selectable soft key is available to receive on-demand advice. The advice is determined using a fuzzy-logic rule based system which provides on-demand advice for the setting of the PSV level and ventilator support levels based upon WOB/min, breathing frequency, tidal volume, ideal body weight, and end-tidal CO_2. The advice is based upon a set of fuzzy logic rules developed and refined in conjunction with experienced critical care clinicians. The rule set is based upon commonly used measures of the patient's respiratory condition including patient effort and ventilation. The predicated Dräger Medical SmartCare™/PS software with the exception of work of breathing/min uses the same measures (i.e. breathing rate, tidal volume and end tidal CO_2)

h. Validation

The validation of the noninvasive work of breathing per minute parameter consisted of (a) validating the front end for esophageal pressure measurement with a cleared device, Bicore CP-100 Cardiopulmonary Monitor, (b) comparing invasive measurements of WOB/min using the esophageal balloon to noninvasive measures of WOB/min derived from proximal flow and airway pressure data collected from ventilated adults in the ICU

(MICU, CICU, SICU, burn unit, step-down unit) who were breathing spontaneously on pressure support ventilation (bias and precision of 0.84 ±2.2 J/min) and (c) validating that the WOB/min algorithm was properly implemented in the embedded system, the Philips NM3 Monitor.

The rule set as implemented in the PS/V Advisor was tested in two separate clinical studies. One study tested if clinicians agreed with the PS Advisor recommendations, and the second study was similar but done blinded so the clinician was unable to see the recommendations of the PS Advisor. A peer-reviewed paper (Banner et al, Chest, 133(3):697-703, 2008) summarizing the results of the first study was published in 2008.

We believe the bench and clinical testing (discussed above) has demonstrated that the VentAssist PS/V advisor is substantially equivalent to the predicate devices cited in section d.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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JUN - 2 2011

Re: K103578
Trade/Device Name: Philips NM3 Monitor with VentAssist, Model 7900
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: II
Product Code: BZK
Dated: May 31, 2011
Received: June 1, 2011

Dear Mr. Mader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103578

Device Name: Philips NM3 Respiratory Profile Monitor with VentAssist, Model 7900

Indications for Use:

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- spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED). Separate combination CO_2/flow sensors are provided for adult, pediatric and neonatal use.
- continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED).

The intended use of the VentAssist software option is to provide:

- non-invasive monitoring of work of breathing per minute in adult patients receiving pressure support mechanical ventilation.
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schutten

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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